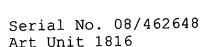


## UNITED STAT PEPARTMENT OF COMMERCE Patent and Tr. Park Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

| SERIAL NUMBER                                            | FILING DATE                                                  | FIRST NAMED INVENTOR                                                         |                                       | ATTORNEY DOCKET NO.               |  |
|----------------------------------------------------------|--------------------------------------------------------------|------------------------------------------------------------------------------|---------------------------------------|-----------------------------------|--|
|                                                          |                                                              |                                                                              |                                       |                                   |  |
| 08/621.723                                               | 5 03/21/96                                                   | LEHMANN                                                                      | F                                     |                                   |  |
|                                                          |                                                              |                                                                              | SCHWADI                               | EXAMINER PON R                    |  |
|                                                          |                                                              | 18M1/0913                                                                    | ART UNIT                              | PAPER NUMBER                      |  |
| PETER G C                                                | ARROLL.                                                      |                                                                              | Antoni                                | 1 1 1                             |  |
| MEDLEN ANI                                               |                                                              |                                                                              |                                       | Ч                                 |  |
| 5017E 220:                                               | u<br>OMERY STREET                                            |                                                                              | 1816                                  |                                   |  |
| SAN FRANC                                                |                                                              | 4                                                                            | DATE MAILED:                          |                                   |  |
|                                                          | rom the examiner in charg<br>TENTS AND TRADEMAR              |                                                                              |                                       | 09/13/96                          |  |
| News                                                     | istaices                                                     |                                                                              |                                       |                                   |  |
| This application has t                                   | oeen <del>examined L</del>                                   | Responsive to communication filed on_                                        |                                       | This action is made final.        |  |
| A shortened statutory per<br>Failure to respond within t | iod for response to this act<br>the period for response will | ion is set to expire month<br>I cause the application to become abar         | (s), 30 days frondoned. 35 U.S.C. 133 | om the date of this letter.       |  |
| Part I THE FOLLOWING                                     | G ATTACHMENT(S) ARE                                          | PART OF THIS ACTION:                                                         |                                       |                                   |  |
| 1. Notice of Refe                                        | rences Cited by Examiner,                                    | . PTO-892. <b>2.</b> 🔲                                                       | Notice of Draftsman's Pa              | tent Drawing Review, PTO-948.     |  |
|                                                          | cited by Applicant, PTO-14                                   |                                                                              | Notice of Informal Patent             | -                                 |  |
| 5. Information on                                        | How to Effect Drawing Ch                                     | nanges, PTO-1474. 6.                                                         |                                       | ·                                 |  |
| Part II SUMMARY OF                                       | ACTION                                                       |                                                                              |                                       |                                   |  |
| 1. Claims 1-                                             | 17                                                           |                                                                              |                                       | _ are pending in the application. |  |
| Of the abov                                              | ve, claims                                                   |                                                                              | are                                   | withdrawn from consideration.     |  |
| 2. Claims                                                |                                                              |                                                                              |                                       | _ have been cancelled.            |  |
| 3. Claims                                                |                                                              |                                                                              |                                       | _ are allowed.                    |  |
| 4.                                                       |                                                              |                                                                              |                                       | are rejected.                     |  |
| 5. Claims                                                |                                                              |                                                                              |                                       | _ are objected to.                |  |
| 6. Claims 1-                                             | 17                                                           |                                                                              | _ are subject to restriction          | on or election requirement.       |  |
| 7. This application h                                    | nas been filed with informa                                  | I drawings under 37 C.F.R. 1.85 which                                        | are acceptable for exam               | nination purposes.                |  |
| 8. Formal drawings                                       | are required in response to                                  | o this Office action.                                                        |                                       |                                   |  |
|                                                          |                                                              | peen received on<br>explanation or Notice of Draftsman's P                   |                                       |                                   |  |
|                                                          | dditional or substitute sheet sapproved by the examiner      |                                                                              | has (have) been                       | approved by the                   |  |
| 11. The proposed dra                                     | awing correction, filed                                      | , has been 🔲 ap                                                              | oproved; disapproved                  | (see explanation).                |  |
|                                                          |                                                              | priority under 35 U.S.C. 119. The cert                                       |                                       | received not been received        |  |
|                                                          |                                                              | dition for allowance except for formal reaccept, 1935 C.D. 11; 453 O.G. 213. | •                                     | o the merits is closed in         |  |
| 14. Other                                                |                                                              |                                                                              |                                       |                                   |  |

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- 15. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
- I. Claims 1-9 are drawn to a method of treating autoimmmune disease, classified in Class 424, subclass 184.1.
- II.Claims 10-17 are drawn to a method of treating an infection, classified in Class 424, subclasses 204.1 and 234.1.
- 16. Inventions I and II are different methods of use. These inventions require different ingredients and process steps to achieve different goals. Invention I is a method of treating autoimmune disease, while invention II is a method of treating infection with a pathogenic organism. Therefore they are novel and unobvious in view of each other and are patentably distinct.
- 17. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II and Groups I and II have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.
- 18. If applicant elects Group I, the following species election is required. This application contains claims directed to the following patentably distinct species of vaccine antigens used in the claimed invention:
  - A) myelin basic protein (claim 3)
  - B) proteolipid protein (claim 4)
  - C) glutamic acid decarboxylase (claim 5)
  - D) intra photoreceptor binding protein (claim 6)
  - E) S-antigen (claim 7)
  - F) renal tubular antigen (claim 8).

These antigens are distinct because they are structurally and functionally different proteins.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims

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shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1,2,9 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

- 19. If applicant elects Group II, the following species election is required. This application contains claims directed to the following patentably distinct species in the claimed invention:
  - A) Intracellular pathogen (claim 12)
  - B) Extracellular pathogen (claims 13,16,17)

These pathogens are distinct because they are structurally and functionally different pathogens.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 10,11,14,15 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant

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with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

- 20. A telephone call was made to Todd Lorenz on 9/3/96 to request an oral election to the above restriction requirement, but did not result in an election being made.
- 21. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
- 22. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).
- 23. Papers related to this application may be submitted to Group

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180 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 180 at (703) 305-7939.

24. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Tuesday through Friday from 8:30 to 6:00. The examiner can also be reached on alternative Mondays. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ms Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1800

Ron Schwadron, Ph.D. Primary Examiner Art Unit 1816 September 11, 1996